

**IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA  
AT CHARLESTON**

<b>IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION</b>	<b>Master File No. 2:12-MD-02327 MDL 2327  JOSEPH R. GOODWIN U.S. DISTRICT JUDGE</b>
<b>THIS DOCUMENT RELATES TO:  WAVE 3 CASES LISTED IN EXHIBIT A TO DEFENDANTS' MOTION</b>	

**REPLY IN SUPPORT OF MOTION TO EXCLUDE OR LIMIT GENERAL-  
CAUSATION TESTIMONY OF DIONYSIOS K. VERONIKIS, M.D.**

Rather than respond to the substantive arguments Ethicon raised for excluding Dr. Veronikis's general-causation opinions, Plaintiffs instead falsely accuse Ethicon of abusing the MDL wave process, ignoring this Court's previous orders, and "improperly seek[ing] reconsideration of the Court's *Daubert* ruling with respect to this witness." Pls.' Opp'n (Dkt. 2890) at 3. But Ethicon did not file a Motion for Reconsideration. Contrary to Plaintiffs' assertions, the MDL Court's pretrial orders expressly contemplate—and indeed *require*—filing a *Daubert* motion with respect to the general-causation experts' opinions on a wave-by-wave basis.

Ironically, it is *Plaintiffs* who seek to reconsider this Court's recent holdings by asking this Court to consider Dr. Veronikis's "general physician" experience as a urogynecologist a sufficient basis for his opinions about what should be included in an IFU. This Court rejected a virtually identical argument in *In re: Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, 2016 WL 4500767, at \*4 (S.D.W. Va. Aug. 26, 2016), where it held that a physician

witness must have “additional expertise” before the physician may offer expert testimony on what information should or should not be included in an IFU. Indeed, Plaintiffs concede that Dr. Veronikis has never designed or consulted on an IFU for an implantable medical device—a fact that confirms, for the purposes of evaluating his qualifications, that Dr. Veronikis lacks the “additional expertise” needed to offer reliable opinions about warnings adequacy.

**I. Ethicon’s motion is not an improper motion for reconsideration.**

As a threshold matter, Plaintiffs’ argument that Ethicon’s motion “improperly seeks reconsideration of the Court’s *Daubert* ruling” ignores this Court’s pretrial orders with respect to the MDL Wave process and wrongly suggests that the issues Ethicon raised are ones that this Court has already considered and denied.

First, under this Court’s Docket Control Orders, Ethicon is limited to filing one *Daubert* motion per general-causation expert with respect to *each wave of cases*, not simply one *Daubert* motion, period, which is what Plaintiffs suggest. Indeed, the Docket Control Order for the Wave 3 Cases specifically scheduled new *Daubert* deadlines for the 200 cases that are unique to Wave 3. *See* Pretrial Order #239 at 4; *see also* Pretrial Order #210. The two *Daubert* documents already filed in this MDL for Waves 1 and 2, do not apply to these 200 Wave 3 cases; indeed, if Ethicon wanted to limit Dr. Veronikis’s general-causation opinions with respect to these cases, they were *required* to file a *Daubert* motion, or Notice of Adoption, as part of Wave 3.<sup>1</sup>

The fact that the parties adopted their Wave 1 *Daubert* motion relative to Dr. Veronikis for Wave 2 is irrelevant; doing so was *not* a requirement of this Court’s Docket Control Orders.

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<sup>1</sup> Plaintiffs implicitly concede this point by acknowledging that the parties filed a Notice of Adoption of their Wave 1 *Daubert* briefing for use in the Wave 2 cases. *See* Pls.’ Opp’n (Dkt. 2890) at 2. If Plaintiffs were correct, then there would have been no need to file notices of adoption and this Court would never have set new *Daubert* deadlines for the general causation experts in Wave 2 or 3.

At that time, this Court had not yet ruled on any Wave 1 *Daubert* motions, and thus there was no reason to alter the parties' briefing. Now that this Court *has* had an opportunity to decide some of the previously briefed issues, filing a new motion is not only appropriate, but actually fosters efficiency by avoiding issues that have already been conclusively decided by this Court.<sup>2</sup> Nor is Ethicon precluded from raising new arguments in this motion that were not previously included in the Wave 1 or Wave 2 Motions, which did not apply to any of the 200 Wave 3 cases. There is simply no basis—and Plaintiffs have cited no authority—for concluding that motions filed with respect to those previous waves have any waiver or preclusive effect on the Wave 3 cases.

**II. In light of this Court's rulings, Dr. Veronikis lacks the "additional expertise" necessary before opining on the adequacy of IFU.**

Contrary to this Court's ruling in its Wave 1 decisions, Plaintiffs insist that Dr. Veronikis's experience as a urogynecologist is sufficient, standing alone, to opine on what warnings should be included in an IFU. This Court, however, held unequivocally that general physician experience is *not* sufficient: "While an expert who is a urologist may testify about the specific risks of implanting mesh and whether those risks appeared on the relevant IFU, *the same expert must possess additional expertise* to offer expert testimony about what information should or should not be included in an IFU." *In re: Ethicon Inc.*, 2016 WL 4500767, at \*4 (emphasis added). While Ethicon is mindful that this decision addressed the opinions offered by a urologist, Dr. Jerry Blavias, the very same principles apply to a urogynecologist like Dr. Veronikis. Simply, the fact that he is a physician—alone—is not enough to qualify him to offer opinions about the content of an IFU given his total inexperience when it comes to drafting or consulting

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<sup>2</sup> To the extent that Ethicon's motion addresses some of the same issues raised in the Wave 1 and Wave 2 Motions, it does so because this Court reserved those issues for decision at trial. This Motion, unlike the Wave 1 and 2 Motions, explains why those decisions can and should be made *prior* to trial, and does not merely rehash the same arguments previously raised.

on IFUs for medical devices. Although Plaintiffs rely on decisions from this Court *predating* its Wave 1 decision, they offer no reason for distinguishing this Court’s Wave 1 decision other than—apparently—the fact that they believe it is wrongly decided. *See* Pls.’ Opp’n (Dkt. 2890) at 5-6. In this sense, it is *Plaintiffs*—not Ethicon—who improperly ask this Court to reconsider an already-decided issue.

Plaintiffs cannot demonstrate the “additional expertise” required for Dr. Veronikis to offer opinions about the adequacy of IFUs by relying on the fact that he has written IFUs for several self-designed surgical instruments. None of these instruments were implantable medical devices, which necessarily require different warnings than surgical tools. Moreover, Plaintiffs do not so much as acknowledge the fact that Dr. Veronikis himself testified that he did not decide *what* went into those warnings; rather, he admitted that “[t]hey gave me a handout on what it should include, and I wrote it.” Ex. D to Defs.’ Mot. (Dkt. 2820-4), Veronikis 4/30/16 Dep. Tr. 164:11-14. Thus Dr. Veronikis did not even have any unique expertise about what goes into the content of IFUs for surgical instruments, much less expertise as to what content should go into an IFU for an implantable medical device.

**III. Plaintiffs do not respond to Ethicon’s arguments for excluding Dr. Veronikis’s opinions about degradation, surgical technique, alternative designs, or his legal conclusions and opinions about Ethicon’s motives, knowledge, and intent.**

Notably, Plaintiffs have chosen not to respond to Ethicon’s arguments with respect to the majority of Dr. Veronikis’s inadmissible opinions, which include his:

- Opinion that TVT mesh is not suitable for implantation because it degrades, frays, and loses particles;
- Opinion that TVT is defective because the surgical technique used is unsafe;
- Opinion that all mesh is unsafe for vaginal use;
- Opinion that Pronova is a safer alternative to Gynemesh PS; and

- Opinions that are legal conclusions or relate to Ethicon's motives, knowledge, and intent.

Contrary to Plaintiffs' assertions, this is not merely a "verbatim" list of Ethicon's previous challenges to which Plaintiffs have already responded. *See* Pls.' Opp'n (Dkt. 2890) at 3. Rather, the arguments Ethicon has raised are tailored to addressing issues left unresolved by this Court's Wave 1 ruling on Dr. Veronikis's opinions.

For example, although Ethicon acknowledges that this Court declined to exclude Dr. Veronikis's fraying and degradation opinions in its Wave 1 ruling because it concluded that "Dr. Veronikis's reliance on Ethicon's internal documents" does not, alone, render his opinions unreliable, *see In re: Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, 2016 WL 4582232, at \*3 (S.D.W. Va. Sept. 1, 2016), Ethicon moves to exclude those same opinions here for a separate reason *not* considered by this Court in Wave 1. Specifically, this Court did not in Wave 1 address whether those opinions should be excluded because Dr. Veronikis himself conceded he had not read any published literature that recognized fraying to be a *clinical problem*. *See* Defs.' Mem. (Dkt. 2821) at 4-5.

Likewise, Plaintiffs have never addressed new issues raised in Ethicon's motion as a response to this Court's Wave 1 ruling, which deferred a decision on several of Dr. Veronikis's opinions. Ethicon has explained why those issues are ripe for and better suited for consideration now as opposed to closer to trial. *See id.* at 6 (addressing why Dr. Veronikis's surgical-technique opinion is inadmissible as a matter of law, and therefore can be decided now), 9 (explaining why Dr. Veronikis's lack of experience with his proposed alternative design requires exclusion of that opinion in all cases). Ultimately, Plaintiffs' silence on these new issues suggests their agreement that this Court is able to address those issues as a matter of law now, as opposed to reserving a ruling until trial.

## CONCLUSION

Ethicon asks this Court to grant its Motion to Exclude the General-Causation Testimony of Dionysios K. Veronikis, M.D., and limit his opinions for the reasons stated above and in its memorandum in support of its motion.

Respectfully submitted,

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**CERTIFICATE OF SERVICE**

I certify that on October 21, 2016, I electronically filed this document with the clerk of the court using the CM/ECF system, which will send notification of this filing to CM/ECF participants registered to receive service in this MDL.

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